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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,998	11/10/2005	Konstantin Konstantinov	07430-00150-USU	1655
23416 7590 01/09/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
			EXAMINER MONDESI, ROBERT B	
			ART UNIT 1652	PAPER NUMBER
			MAIL DATE 01/09/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/532,998

Applicant(s)

KONSTANTINOV ET AL.

Examiner

Robert B. Mondesi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 May 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Priority***

The current application filed on November 10, 2005 is a 371 of PCT/US03/34522 filed 11/01/2003 which claims benefit of 60/422,999 filed 11/01/2002.

### ***Preliminary Amendment***

The preliminary amendment filed April 28, 2005 has been entered.

### ***Drawings***

The drawings are objected to because Figures 1 contains text that appear to be description of the drawing and not related to an office acceptable legend under 37 CFR 1.84(o), such description belongs in the Brief Description of the Drawings in the specification of the application (The mentioned text appears below the Fig.). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement-drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet"

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pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Information Disclosure Statement***

The IDS filed April 28, 2005 and October 31, 2006 have been received and are signed and considered; a copy of the PTO 1449 is attached to the following document.

***Specification***

The disclosure is objected to because of the following informalities:

The use of the trademark PLURONIC F-68 has been noted in this application (Page 2, line 15). It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claim 7** is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

**Claim 7** contains the trademark/trade name PLURONIC. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polyoxyethylene-polyoxypropylene block co-polymer or polyoxyethylene-polyoxypropylene glycol and, accordingly, the identification/description is indefinite.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rancke-Madsen et al., U.S. Patent No. 6,087,148 in view of Koch et al., U.S. Patent No. 6,143,331 and Schulz et al., 1997 (cited in the IDS filed 28, April 2005).

Rancke-Madsen et al. teach a method for concentrating macromolecules comprising fermentation broth containing a protein and other fermentation by-products wherein the broth was subjected to drum-filtration and then ultrafiltration (using Dow DDS Gr61pp membranes; cut-off ca. 20 kD). The ultrafiltration concentrate was further subjected to diafiltration using 2 volumes of deionized water to remove low-molecular-weight substances (such as salts). The resulting solution contained 87 grams of cellulase per liter (constituting 51% w/w of the dry-matter content of the solution), and had a pH of 6.7 and a specific conductivity of 0.7 mS/cm (Example 1, column 10, lines 20-31).

Rancke-Madsen et al. do not teach that multiple ultrafiltration steps were used in the method of concentrating macromolecules or that F-68 was the organic polymer used in the fermentation broth.

Koch et al teach a subsequent ultrafiltration step wherein the second ultrafiltration is conducted with an ultrafiltrate on the membrane with an exclusion volume of 3 kD is also preferably conducted several times, but particularly at least three times, and preferably at least five times. It has also proven appropriate to conduct this latter ultrafiltration step as a so-called diafiltration, i.e., as a repeated filtration, whereby,

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analogously to a dialysis, undesired components are washed out by multiple filtration with the filtrate solution through the filter. In this way it is possible, without anything further, to separate substances entrained with the extraction solution, such as, for example, buffer salts, and to replace by other additives. It is preferred according to the invention to dilute the retentate concentrated by means of the second ultrafiltration on the 3-kD membrane with a mannitol solution and to repeat the filtration. In this way, the extraction solution can be rebuffed in a simple way. The retentate obtained in this way according to the invention can be lyophilized without anything further while retaining its biological activity (column 2, lines 30-50).

Schulz et al. teach that ultrafiltration (UF) is one of the most efficient processes recommended as a first step in downstream procedures for the recovery of proteins from mammalian cell cultivation. Cell culture supernatants consist of a broad spectrum of compounds, which influence the performance of UF. These include supplements of the culture medium (e.g. Pluronic F-68, silicone oil) or compounds that are secreted from the cells or released after cell lysis (e.g. proteins, lipids). The nonionic block copolymer Pluronic F-68 is often supplemented to cell culture media in order to protect mammalian cells from shear stress caused by sparging. The overall performance of ultrafiltration processes strongly depends on solute-membrane interactions, since these different substances can adsorb onto the external or internal membrane surface and influence permeability and retention. Additionally, information about the fouling tendency as well as the cleaning property of the membranes is important for an optimal

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design of the UF process (introduction, page 1, paragraph 2, through page 2, paragraph 1).

The claims would have been obvious because "a person of ordinary skill in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense."

The US Federal Circuit has recently explicitly stated that in order to make a *prima facie* case of obviousness, the suggestion and motivation to combine said references need not be explicitly stated in the text of the references. Rather, consideration of common knowledge and common sense when combining references is not only permitted *but required*. See *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 80 USPQ2d 1641 (Fed. Cir. 2006) which states:

"'Suggestion' test for obviousness does not require that suggestion, teaching, or motivation to combine cited prior art references be found in references themselves, or that such suggestion or motivation be explicitly stated; suggestion test is flexible rather than rigid and categorical, recognizing motivation to combine found in knowledge of persons of ordinary skill in art or nature of problem to be solved, as well as in references, and test not only permits, but requires, consideration of common knowledge and common sense."

### **Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B. Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert B Mondesi/  
Examiner  
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January 7, 2008

RBM